



## **Urgent Field Safety Notice**

### **Invacare RELIANT 350 Lifter – Incorrect SN labels**

Date: 10<sup>th</sup> July 2015

**Invacare Ref: FSN 354843**

MHRA Ref: 2015/007/014/291/018

#### **Important Safety Information:**

In the interests of the safety of our customers Invacare would like to you of an error affecting a small batch of serial number labels on RELIANT 350 lifters.

The RELIANT 350 complies in full with all applicable requirements for Medical devices, class I products, according to Medical devices directive 93/42/EEC.

Due to a print error of these serial number labels since **March 2015 – after SN 15CSZ970001**, the maximum user weight is stated incorrectly on the serial number labels placed on the products. Please note that the notice on the mast of the Reliant 350 has not been affected and clearly displays the correct limit of 159 kg.

A list of affected product in UK is shown below, however, please be advised that if you have purchased products from within the affected serial number ranges you will be notified separately by Invacare.

#### Serial Numbers of Affected Product:

15CSZ100001, 15CSZ100002, 15CSZ100003, 15CSZ100004, 15CSZ100005, 15CSZ100006  
15CSZ100013, 15CSZ100014, 15CSZ100015, 15CSZ100016, 15CSZ100019, 15CSZ100031  
15CSZ100033, 15CSZ100034, 15CSZ100035, 15CSZ100036, 15CSZ100041, 15CSZ100045  
15CSZ100047, 15CSZ100048, 15CSZ100054, 15CSZ100055, 15CSZ100056, 15CSZ100057  
15CSZ100072, 15CSZ100074, 15CSZ100078, 15CSZ100079, 15CSZ100083, 15CSZ100088  
15CSZ100089, 15CSZ100090, 15CSZ100091, 15CSZ100092, 15CSZ100098, 15CSZ100105  
15CSZ100106, 15CSZ100107, 15CSZ100110, 15CSZ100115, 15CSZ100123, 15CSZ100124  
15CSZ100125, 15CSZ100134, 15CSZ100136, 15CSZ100143, 15CSZ100144, 15CSZ100146  
15CSZ100158, 15CSZ100162, 15CSZ100163, 15CSZ100165, 15CSZ100179, 15CSZ100180  
15CSZ100181, 15CSZ100182, 15DSZ100004, 15DSZ100005, 15DSZ100006, 15DSZ100012  
15DSZ100017, 15DSZ100018, 15DSZ100019, 15DSZ100025, 15DSZ100026, 15DSZ100027  
15DSZ100030, 15DSZ100031, 15DSZ100042, 15DSZ100043, 15DSZ100044, 15DSZ100045  
15DSZ100046, 15DSZ100047, 15DSZ100048, 15DSZ100052, 15DSZ100056, 15DSZ100057  
15DSZ100058, 15DSZ100059, 15DSZ100061, 15DSZ100064, 15DSZ100068, 15DSZ100073



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15DSZ100078, 15DSZ100079, 15DSZ100084, 15DSZ100085, 15DSZ100086, 15DSZ100087  
15DSZ100088, 15DSZ100096, 15DSZ100125, 15DSZ100126, 15DSZ100127, 15DSZ100145  
15DSZ100158, 15DSZ100159, 15DSZ100161, 15DSZ100162, 15DSZ100163, 15DSZ100173  
15DSZ100174, 15DSZ100175, 15DSZ100193, 15DSZ100194, 15DSZ100195, 15DSZ100205  
15DSZ100206, 15DSZ100207, 15DSZ100217, 15DSZ100218, 15DSZ100219, 15DSZ100230  
15DSZ100231, 15DSZ100233

Customers are kindly requested to exchange the new serial number label with the correct maximum user weight (159 Kg) on the affected Invacare RELIANT 350 lifters and to report back to Invacare when this is done, using the attached Fax back document.

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base, and / or any organisation where the potentially affected devices have been transferred. Please also ensure that awareness is maintained for an appropriate period.

Invacare acknowledges that this may be an inconvenience; however it is not an option and must be done immediately to mitigate the potential safety risk.

If you have any questions relating to this bulletin, or should you require any additional information, please contact;

### **Technical Services Department**

Tel. 01656 776333

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Invacare confirm that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.



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